Contact Person: Linda Martin (804) 737–6010.

Project Title: Texas—Achieving Change for Texans.

Description: Statewide, would implement requirement for a personal responsibility agreement which addresses issues such as child support cooperation, early medical screening for children, work requirements, drug and alcohol abuse, school attendance, and parenting skills training; would limit the caretaker exemption from employment services, disregard the earned income and resources from earnings of a child, set resource limits which promote independence from AFDC, eliminate work history and 100-hour rules for otherwise eligible two-parent families. In Bexar County would time-limit AFDC benefits to 12, 24, and 36 months depending on education and job experience, with extensions of the time-limit based on severe personal hardship, or in cases where the State could not provide supportive services, or the where the local economy was in such state that the recipient could not reasonably be expected to find employment, if State funds are available to continue assistance. Transitional Medicaid and child care services would be provided to individuals who exhaust their time-limited cash benefits. In two metropolitan statistical areas establish Individual Development Accounts to promote the transition to independence from AFDC, through allowable account deductions for education, business start-up costs and the like. In Fort Bend County would allow at recipient option, one-time AFDC cash emergency assistance payments of $1,000 in lieu of ongoing regular AFDC payments with prohibition from applying for regular AFDC for a period of 12 months from date of receipt. In Dallas-Fort Worth would require electronic imaging (fingerprinting combined with photographic identification).

Date Received: 10/6/95.

Title: AFDC/Medicaid.

Current Status: Pending.

Contact Person: Kent Gummerman, (512) 438–3743.

Project Title: Utah—Untitled.

Description: Statewide, would exclude the value of a vehicle for AFDC recipient families, including those also receiving Food Stamps. Would not apply to initial eligibility determination.

Date Received: 10/3/95.

Type: AFDC.

Current Status: Pending.

Contact Person: Bill Biggs, (801) 538–4337.

III. Listing of Approved Proposals since November 1, 1995

None.

IV. Requests for Copies of a Proposal

Requests for copies of an AFDC or combined AFDC/Medicaid proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of a proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research)

Dated: December 1, 1995.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 95–29823 Filed 12–6–95; 8:45 am]

BILLING CODE 4184–01–P

Agency for Health Care Policy and Research

Availability of Draft Clinical Practice Guideline on Smoking Cessation for Pre-Publication Review

AGENCY: Agency for Health Care Policy and Research.

ACTION: Notice.

SUMMARY: The Agency for Health Care Policy and Research (AHCPR) announces the availability of a draft AHCPR-sponsored clinical practice guideline on smoking cessation for pre-publication review. This guideline is being produced by a multidisciplinary private-sector panel of experts convened by AHCPR. The expert panel will not respond to individual comments but will consider all comments in determining revisions to the guideline. Individuals interested in obtaining a copy of the draft guideline for review must agree not to disclose its content to the public prior to its publication by AHCPR.

DATES: Comments must be postmarked by January 4, 1996.

SUPPLEMENTARY INFORMATION: The Agency for Health Care Policy and Research is responsible for the development of clinical practice guidelines that may be used by physicians, other health care practitioners, educators, and consumers to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and clinically managed. The AHCPR facilitates the development of guidelines by establishing private-sector panels who are responsible for their content.

A private-sector panel of health care experts and consumers was formed in May, 1994 to develop a clinical practice guideline to improve the effectiveness of smoking cessation activities. A public meeting was also held in November, 1994 for the panel to receive comments and information relevant to development of the guideline. The panel has reviewed and synthesized the literature on this topic and drafted a set of conclusions and recommendations based on the best available scientific data and expert judgment.

A draft of these conclusions and recommendations is now undergoing peer review by a substantial number of individuals and groups who are knowledgeable about smoking cessation programs and related activities. With this notice, the panel and AHCPR are also making the draft guideline available to any person who wishes to review and comment on it, so long as the person agrees to honor the confidentiality of this draft (as specified below).

After review of all comments received, the panel will revise the draft guideline and prepare the clinical practice guideline on smoking cessation.

Potential reviewers should note that AHCPR may disclose the names of the guideline reviewers at the same time the guideline is published. The AHCPR may also release the review comments after the guideline is published. However, the comments will not be attributed to specific reviewers.

Confidentiality Statement for Reviewers

During the review process, and until published by AHCPR, the guideline is confidential. It may not be quoted, distributed, or copied without the prior written consent of the panel chair.

All requests for the draft guideline must include the following confidentiality statement signed by the requestor:

In order to protect the integrity of the panel's deliberative process and its final product, I agree that: I will not release, publicly present, publish, have published, or otherwise disseminate any portion of the draft Smoking Cessation guideline.

Signature _____

Date _____

Affiliation _____

Name (printed or typed) _____

Request for Draft Guideline

To receive a copy of the draft guideline, requests must include: Requestor's name; Affiliation (business or organization); Address (including zip code); Telephone and Fax numbers; Signed confidentiality statement; and Information on reviewer's computer resources, if applicable, (needed to

ascertain ability to use a computerized program for guideline review).

Written requests, together with the signed confidentiality statement, should be mailed to: Cheryl Campbell, Panel Manager; Technical Resources International, Inc. (TRI), 3202 Tower Oaks Boulevard, Rockville, Maryland 20852–4200. (Fax number: (301) 231–6377.) If faxing the request, the original signed confidentiality statement must also be mailed.

Automated review process: A computerized guideline review process, supported by AHCPR, enables comments to be entered on a specially formatted diskette. A diskette will be furnished, with instructions, to those requesting the draft guideline. To facilitate the review process, it is recommended that reviewers use the computer diskette to record their comments. Reviewers who do not use a diskette will be asked to provide typewritten comments.

Requests for a copy of the draft guideline should include the following information regarding the computer system to be used for reviewing the guideline: Type of computer: IBM/compatible or Macintosh; and if IBM/compatible: the size of disk drive (3.5″ or 5.25″).

For technical assistance or questions regarding computer resources, call the Guideline Review Technical Support at (301) 231–5250 ext. 100 and ask for Ms. Cheryl Campbell.

FOR ADDITIONAL INFORMATION: Additional information on the guideline development process is contained in the AHCPR Program Note, ''Clinical Practice Guideline Development,'' (AHCPR Publication No. 93–0023) dated August 1993.

This document may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; or call toll-free: 1–800–358–9295.

Dated: December 1, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–29865 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 95E–0300]

Determination of Regulatory Review Period for Purposes of Patent Extension; CELLCEPT®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CELLCEPT® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CELLCEPT® (mycophenolate mofetil). CELLCEPT® is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CELLCEPT® (U.S. Patent No. 4,753,935) from Syntex, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 2, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CELLCEPT® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CELLCEPT® is 2,479 days. Of this time, 2,304 days occurred during the testing phase of the regulatory review period, while 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 21, 1988. The applicant claims June 24, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 1988, which was 30 days after FDA receipt of IND 31,747 on June 21, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: November 10, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for CELLCEPT® (NDA 50–722) was initially submitted on November 10, 1994.

3. *The date the application was approved*: May 3, 1995. FDA has verified the applicant's claim that NDA 50–722 was approved on May 3, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 824 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the